



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0601; FRL-9918-88]

Alpha-cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of alpha-cypermethrin in or on food commodities/feed commodities in food/feed handling establishments.

BASF on behalf of Whitmire Micro-Gen Research Laboratories requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0601, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)

566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0601 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0601, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8189) by BASF on behalf of Whitmire Micro-Gen Research Laboratories, 3568 Tree Court Industrial Blvd., St. Louis, MO 63122-6682. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide alpha-cypermethrin, in or on food/feed handling establishments at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared by BASF on behalf of Whitmire Micro-Gen Research Laboratories, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

EPA has corrected the proposed commodity definition to read food commodities/feed commodities (other than those covered by a higher tolerance as a results of use on growing crops) in food/feed handling establishments.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for alpha-cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with alpha-cypermethrin follows.

Alpha-cypermethrin is an enriched isomer of the pyrethroid insecticide cypermethrin. In addition, zeta-cypermethrin is also an enriched isomer of cypermethrin. The toxicology database for the cypermethrins includes studies with cypermethrin and both of its enriched isomers, and is considered complete for the purpose of risk assessment. When considering alpha-cypermethrin the EPA also considers potential exposures from the other registered cypermethrins (i.e., cypermethrin and zeta-cypermethrin), since the 3 active ingredients are essentially the same active from the mammalian toxicity perspective. The recommended tolerance of 0.05 ppm associated

with the food handling establishment use of alpha-cypermethrin is at the same level as the one currently established for zeta-cypermethrin. Based on the available alpha-cypermethrin residue data submitted for the food handling establishment use, this use will not result in alpha-cypermethrin residues higher than 0.05 ppm and is the same as the existing tolerance of 0.05 ppm established to support the food handling establishment uses for zeta-cypermethrin. The existing dietary and aggregate risk assessments already account for the impact of the existing zeta-cypermethrin food handling establishment use (i.e. 100% crop treated for all commodities without an existing tolerance). Therefore, the addition of the food handling establishment use for alpha-cypermethrin will have no impact on the dietary risk estimates, as they are already covered in the existing dietary and aggregate risk assessments.

In the **Federal Register** of February 1, 2013 (78 FR 7266) (FRL-9376-1), the EPA published a final rule to establish tolerances for residues of the insecticide alpha-cypermethrin in or on alfalfa, hay at 15 ppm; citrus, dried pulp at 1.8 ppm; citrus fruit, Group 10 at 0.35 ppm; citrus, oil at 4.0 ppm; corn, grain; cottonseed; cucurbit vegetables, Group 9; dried shelled pea and bean, except soybean, subgroup 6C; edible podded legume vegetable, subgroup 6A; fruiting vegetables, Group 8; head and stem Brassica, subgroup 5A at 2.0 ppm; leafy vegetable, except Brassica, Group 4 at 10 ppm; pop-corn; rice, grain at 1.5 ppm; root and tuber vegetables, Group 1 at 0.1 ppm; sorghum, grain at 0.5 ppm; soybeans; succulent shelled pea and bean, subgroup 6B; sugar beet, roots at 0.05 ppm; sugar beet, tops; sweet corn; tree nuts, Group 14; and wheat, grain at 0.2 ppm. Since the publication of the February 1, 2013 final rule, the toxicity profile of alpha-cypermethrin has not changed and since the food handling establishment use for alpha-

cypermethrin will have no impact on the dietary or aggregate risk estimates, the risk assessments that supported the establishment of those alpha-cypermethrin tolerances published in the February 1, 2013 **Federal Register** remain valid. Therefore, EPA is relying on those risk assessments in order to support the new food handling tolerance for alpha-cypermethrin.

For a detailed discussion of the aggregate risk assessments and determination of safety for the food handling tolerance, please refer to the February 1, 2013 **Federal Register** document and its supporting documents, available at <http://www.regulations.gov> in Docket ID number EPA-HQ-OPP-2010-0234. EPA relies upon those supporting risk assessments and the findings made in the **Federal Register** document in support of this final rule.

Based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to alpha-cypermethrin residues. Further information can also be found in the document, “Alpha-Cypermethrin - Human Health Risk Assessment for Two New Proposed Products for Use in Commercial/Residential Settings” in docket ID number EPA-HQ-OPP-2014-0601.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in Pesticide Analytical Manual (PAM) Volume II for determining residues of cypermethrin, zeta-cypermethrin and alpha-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD),

and have undergone successful Agency petition method validations (PMVs). Method I has a limit of detection (LOD) of 0.01 ppm, and Method II has LODs of 0.005 ppm in milk, and 0.01 ppm in livestock tissues. These methods are not stereospecific; thus no distinction is made between residues of cypermethrin (all eight stereoisomers), zeta-cypermethrin (enriched in four isomers) and alpha-cypermethrin (two isomers).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There is no Codex MRL for residues of alpha-cypermethrin in or on food commodities/feed commodities (other than those covered by a higher tolerance as a results of use on growing crops) in food/feed handling establishments.

C. Response to Comments

The EPA received 4 comments in response to this Notice of Filing. Two commenters were opposed to increasing the amount of pesticides being used and did not approve of the proposal. The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when EPA determines that aggregate exposure to that pesticide is safe, i.e., that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. When making this determination, EPA considers the toxicity, including any potential carcinogenicity, of the pesticide and all anticipated dietary exposures and all other exposures for which there is reliable information. EPA also gives special consideration to the potential susceptibility and exposures of infants and children to the pesticide chemical residue when making this determination. For alpha-cypermethrin, the Agency has considered all the available data, including all available data concerning the potential for carcinogenicity and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm will result from aggregate human exposure to alpha-cypermethrin.

Two additional commenters raised concerns regarding exposure to bees. However, the proposed use is for pesticide applications to be made indoors to food/feed handling establishments and therefore, there should be no exposure to bees from the proposed application.

V. Conclusion

Therefore, the tolerance is established for residues of alpha-cypermethrin, in or on food commodities/feed commodities (other than those covered by a higher tolerance as a results of use on growing crops) in food/feed handling establishments at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 26, 2014.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.418, revise the section heading and add alphabetically the following commodity to the table in paragraph (a)(3) to read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

(a) * * *

(3) * * *

Commodity	Parts per million
* * * *	* * *
Food commodities/feed commodities (other than those covered by a higher tolerance as a results of use on growing crops) in food/feed handling establishments	0.05
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[FR Doc. 2014-28934 Filed 12/09/2014 at 8:45 am; Publication Date: 12/10/2014]